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Assessment of Private Sector Prospects for Reproductive Health and Family Planning Products and Services in Ukraine

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Mission

Private Sector Partnerships-*One* (PSP-*One*) provides technical leadership to promote and expand the private sector's interest, ability and direct involvement in the delivery of quality reproductive and other health products and services.

To increase private and commercial sector participation in the sustainable provision of reproductive and other health products and services PSP-*One* works to:

- ❖ Advance private sector programming knowledge and practices
- ❖ Facilitate public/private alliances
- ❖ Pursue optimal market segmentation
- ❖ Promote behavior change through targeted health communications
- ❖ Upgrade private provider performance
- ❖ Expand financial mechanisms to improve access to health products and services
- ❖ Improve policy and regulatory environments
- ❖ Scale up proven private sector models and strategies

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Acronyms

| | |
|-----------------|--|
| PSP- <i>One</i> | Private Sector Partnerships- <i>One</i> project |
| USAID | United States Agency for International Development |
| A&P | advertising and promotional |
| BCC | behavior change communication |
| CIF | cost, insurance and freight (included) |
| FP | family planning |
| CIDA | Canadian International Development Agency |
| HIV/AIDS | human immune deficiency virus/acquired immune deficiency virus |
| IUD | intra-uterine devices |
| JSI | John Snow, Inc. |
| GDP | gross domestic product |
| MOH | Ministry of Health |
| NGO | non-government organizations |
| NRHP | National Reproductive Health Program |
| OC | oral contraceptives |
| OTC | over-the-counter |
| PDG | policy development group |
| RH | reproductive health |
| STI | sexually transmitted infections |
| UAH | Ukrainian Hryvnia |
| UNFPA | United Nations Funds for Population Fund |
| UNICEF | United Nations Children's Fund |
| URHS | Ukraine Reproductive Health Survey |
| USAID | United States Agency for International Development |
| WRHI | Women's Reproductive Health Initiative |

Executive Summary

Ukraine is a middle-income country with increasing economic prospects, a thriving private sector market, and widespread access to affordable health services. The country is however experiencing reproductive health issues similar to those of other former soviet republics. Among these are the limited use of modern contraceptive methods, high method failure and abortion rates, a growing incidence of sexually transmitted infections (STI) and critical information gaps among providers and potential users alike.

Ukraine is also a country characterized by a wide reaching public health sector with a highly medicalized approach to reproductive health. In contrast to services, however, pharmaceutical products are almost exclusively accessed through private sector pharmacies and there is no systematic policy of providing free or subsidized contraceptives to the public. Concerned about potential gaps in contraceptive security, the USAID/Ukraine mission requested from the PSP One project an assessment of the private sector's current and potential contribution to RH/FP needs, particularly in the area of contraceptive supply.

In addition to assessing the current supply of products and services, the PSP One team also set out to analyze the factors that are known to predict contraceptive security, such as the demand for products, the effectiveness of commercial distribution channels, the role of service providers, the level of effort invested in consumer campaigns, and public sector policies as they affect private sector performance.

Key findings of the team's analysis include the following:

Policy environment

The PSP team conducted a legal and regulatory assessment of market conditions for the private sector provision of FH/RH products and Services. Overall, the legal and regulatory framework and policy environment create positive incentives for private investments, encouraging the entry and sustained presence of private sector suppliers in the FP/RH market place. The policy environment, however, has traditionally not been supportive of NGOs as providers of RH/FP products and services. Although NGOs activities have recently been granted the right to provide FP/RH clinical services, it is highly unlikely that many will take advantage of these changes because of a prohibition on charging fees and limited access to capital.

Some regulations exist that may restrict access to prescription drugs, limit the provision of RH/FP information to minors, and prevent consumer-directed advertising campaigns. More significant than laws and regulations, however, may be the impact of perceptions and practices on consumer and provider behaviors. For example, youth do not spontaneously seek counseling and services from public clinics; consumers routinely obtain products without prescriptions; and pharmaceutical companies typically prefer dealing with providers than consumers. Furthermore, if policies and regulations do not restrict any FP contraceptive method, provider practices and user preferences have resulted in a skewed method mix that relies heavily on abortion, traditional methods and increasingly, hormonal contraceptives.

Product supply

The current range of modern contraceptive products available on the Ukrainian commercial market includes condoms, oral and injectable contraceptives, and intra-uterine devices, with hormonal contraception representing the fastest growing segment of the market. While products are available at different price points, the saturation of the supply side of the market and increased competition for market share have led pharmaceutical companies to focus on their core consumer group and loyal providers rather than potential new users. Contraceptive manufacturers have played a critical role in increasing provider confidence in hormonal contraception, notably by supporting continued education for health providers. The general public, however, is seldom the focus of information and public relations campaigns, which in turn contributes to the sluggish demand for contraceptives.

Commercial contraceptive brands are distributed through a vast network of wholesalers and retailers whose potential reach extends to all regions of Ukraine, including rural areas. The industry is undergoing a consolidation phase characterized by the closing of wholesalers, but the number of pharmacies remains high. Pharmaceutical sales are a highly profitable business in Ukraine, fueled by a growing demand for products that must be met almost exclusively by the private sector. This market, however, suffers from a lack of reliable data about contraceptive product sales, market share, consumer trends and distribution coverage.

RH/FP services

The Ukrainian RH environment is characterized by a continued dominance of the public sector in the area of services. There is, however, little supervision of the relationship between public sector providers and the pharmaceutical industry, which is characterized by much-needed private sector support for provider training, but also alleged unethical behaviors by some pharmaceutical companies. This close relationship appears to have fostered a growing preference for prescribing oral contraceptives and a decreasing reliance on other methods such as IUDs and injectables.

There appears to be very few incentives for the provision of reproductive health services through privately owned practices and clinics. Direct payments of public sector providers by patients have had the effect of creating an informal private sector within the MOH. Although this shadow market has resulted in widespread acceptance of the principle of fee for service, it has also reduced incentives for doctors to set up their own practice, which involves considerable risks and costs. Providers working in private sector clinics tend to concentrate on profitable services and leave preventive services, such as family planning, to the public sector. Furthermore, few Ukrainians are able to afford private sector service fees, which are considerably higher than informal payments in public clinics.

With the bulk of reproductive health services currently provided by public sector facilities, and the concentration of product supply in the commercial sector, there is limited room left for non-profit organizations to play a significant role in reproductive health. Although a recent law has made it possible for NGOs to provide services and products to patients, there seem to be a very limited number of organizations in Ukraine with the human, technical and structural capacity to become service providers. NGOs, however, can play a critical role in addressing the need for RH/FP information in the general population through consumer-directed communication campaigns and other IEC activities.

In light of the above findings, the team offered the following conclusions:

- There is no pressing contraceptive security problem in Ukraine where products are concerned, as the commercial market caters to a large proportion of the user population and the sustained presence of affordable brands does not appear to be threatened
- The lack of research data, however, leaves some contraceptive security questions unanswered. The ability of people living in rural areas, young people and the urban poor to access and afford contraceptives can only be determined through quantitative research.
- Widespread access to products and services does not extend to accurate and reliable information on FP/RH. Public and private sector providers, as well as OC manufacturers, agree that lack of information and education among potential users is the biggest barrier to increased use of modern methods.
- The current method mix is driven by industry pressure and provider attitudes rather than public health goals, resulting in a trend toward a limitation of options for Ukrainian women.
- Efforts to bolster the development of private sector practices are unwarranted at the present time, because the current division of responsibilities between the public and private is unlikely to change. Policy efforts should therefore focus on correcting problems rather than changing the status quo.

Consequently, PSP One recommends avoiding supply-side activities that may have a counterproductive effect on the commercial contraceptive market, focusing instead on increasing demand for products and services among key target groups. This can be achieved in collaboration with contraceptive manufacturers that are actively investing in the contraceptive market. PSP One also recommends addressing gaps in knowledge and misconceptions among service providers, and supporting more ethical practices between product suppliers and service providers. Potential gaps in contraceptive security remain to be identified through quantitative research and should be addressed through carefully targeted public sector or NGO programs.

In order to increase sustained private sector participation to RH/FP Goals, the PSP One team advocates a dual strategy of public/private partnerships and public sector policies that facilitate and complement the activities of the private sector.

Proposed illustrative partnership activities include:

- Working with the pharmaceutical industry to design and implement consumer campaigns, increase distribution coverage in under-served areas, and ensure the wide availability of affordable products
- Supporting ethical provider outreach activities by pharmaceutical companies, including public relations campaigns, expanded pharmaceutical detailing, and controlled product sampling programs

-
- Supporting and expanding the activities of NGOs with technical expertise and experience in dealing with target groups, as well as those involved in advocacy and provider training

Proposed illustrative policy interventions include:

- Helping the MOH formalize public/private partnerships through a memorandum of understanding, and the development of a National Contraceptive Security Strategy
- Conducting a segmented market analysis to identify characteristics of potential users and under-served groups, and strategies to meet their needs
- Designing a commodities distribution program to be channeled through select public outlets and providing technical assistance to the MOH in targeting commodities to priority populations
- Supporting large scale contraceptive technology updates for MOH gynecologist, obstetricians and family medicine doctors, and encouraging a more balanced method mix through evidence-based prescribing practices

1. Background

1.1 Country Overview

Ukraine, a country of 48.4 million people¹ with an annual GDP per capita of \$5,400², faces reproductive health challenges similar to those of other countries in the former Soviet Union. In spite of an improving economic situation, fertility rates have been low, contributing to a decline in population of more than 2 million people from 1991 to 2001. Maternal and infant mortalities have improved recently, though rates are still high in comparison to other European countries, and the spread of sexually transmitted infections (STI) and HIV/AIDS is on the rise. Other major RH issues include a low use of modern contraception methods and a high level of unintended pregnancies and abortions³.

A number of programs have been implemented to address these problems since the collapse of the Soviet Union, many of them supported by USAID/Ukraine. In 1995, the Ministry of Health (MOH) launched the Women's Reproductive Health Initiative (WRHI) to carry out provider training, information, education, and communication (IEC) activities, policy improvement initiatives, and commodities procurement. USAID also supported the Policy Development Group (PDG) and the Ukraine Reproductive Health Network (URHN), and funded a 5 year National Reproductive Health Plan (NRHP) and the 1999 Ukraine Reproductive Health Survey (URHS), which remains the most recent reliable source of RH information⁴. Other donor organizations currently working in the RH/FP area in Ukraine include the United Nations Population Fund (UNFPA), the European Union (EU), the United Nations Children's Fund (UNICEF), and the Canadian International Development Agency (CIDA).

Efforts to improve the RH/FP situation in Ukraine have contributed to a high overall contraceptive prevalence (68%). The use of modern methods, however, remains low with only 38% of couples using a method. Other areas of concern include high abortion levels (the NRHP estimates that 1.2 abortions are performed for each birth⁵), high contraceptive failure and discontinuation rates, and inconsistent RH/FP knowledge among both the general population and provider community. In particular, the 2003 POPTECH assessment pointed to "missed opportunities" in the area of postpartum and post abortion counseling, and unmet RH needs in the youth population.

Ukraine's high abortion rate and low use of modern methods are sometimes interpreted as a consequence of limited access to contraceptives. In particular, the lack of sustained subsidized commodities program is often cited as a significant barrier for low-income and hard-to-reach groups. Another concern is access to reliable information, since many people obtain contraceptive products directly from pharmacies, where little RH/FP counseling is provided. Previous projects

¹ 2001 Census

² Purchasing power parity, 2004 estimate. CIA World Factbook

³ POPTECH Assessment of Reproductive and Maternal Health in Ukraine, LTJ Associates, Inc. December 2003

⁴ POPTECH 2003

⁵ National Reproductive Health Program 2001-2005, December 2000

and assessments have resulted in numerous recommendations for improvement. Among those, increased private sector commitment to quality RH/FP programs has been suggested as a way to ensure contraceptive security and grow the use of modern methods in Ukraine.

1.2 Objectives of the Assessment

The USAID/Ukraine mission requested technical assistance from the Private Sector Program core task order (PSP-*One*) in assessing the ability of the private sector to contribute to contraceptive security in Ukraine. In particular, the PSP-*One* team was expected to address the current and estimated future availability, affordability and accessibility of contraceptives in the private sector. This report presents the team's findings, provides recommendations for activities and policies that can increase private sector engagement in the contraceptive field, identifies specific population groups not likely to be adequately served by the private sector, and suggests strategies to meet their needs while avoiding negative impact on the growing contraceptive market.

1.3 Approach

The PSP-*One* team first sought to identify and interview key players in the private contraceptive market, including pharmaceutical manufacturers, distributors, wholesalers and retailers, and private medical providers. In addition, we explored the impact of public sector policies and practices, as well as the activities of nonprofit organizations, on the demand for and supply of contraceptive methods. Because for-profit companies in particular tend to react to market conditions as they evolve, the team aimed to fully understand current and future governmental policies in order to predict likely responses in the private sector.

The PSP-*One* team adopted a holistic approach to the concept of contraceptive security. The availability and affordability of contraceptive methods in a given country are directly influenced by the following factors:

- The current demand for products and services at commercially sustainable prices
- The competitive landscape for contraceptive products and services
- The size and complexity of the commercial distribution infrastructure
- The availability and affordability of health services related to contraceptive methods
- The attitudes and behaviors of key influencers, such as the medical community
- The level of effort invested in demand-building activities such as generic and branded advertising, and targeted behavior change communication (BCC)
- The availability of free and/or subsidized products and services in the country

In determining realistic strategies to maximize private sector involvement and meet contraceptive security needs in Ukraine, the team also took into consideration corporate interests and priorities, user preferences, and financial sustainability requirements.

2. Market Analysis

2.1 Policy environment and its impact on the private sector

The PSP-*One* team culled through the literature and policy documents to identify any policy barriers to private sector provision of FP/RH services and obstacles to contraceptive security. In addition, interviews were used to identify any departure from laws, policies and regulations and practice. The results of this analysis are presented in Annex 2 -Legal and Regulatory Assessment of Market Conditions for Private Sector Provision of FH/RH products and Services. Below are highlights of the analysis:

Overall, the legal and regulatory framework and policy environment are very favorable to the private sector. Major laws and regulations that influence the supply of FP/RH products are very liberal, creating positive incentives for the commercial sector to invest in RH/FP activities. Policies in the areas of: (i) tax and import policies; (ii) product approval, licensing and registration; (iii) price controls and profit limits, and; (iv) advertising and promotion regulations, are market oriented and do not present barriers to private sector entry and sustained presence in the FP/RH market place.

Policies and regulations do not restrict any FP contraceptive method, allowing for a balanced method mix. By law, every modern method –pills, intra-uterine devices, injectables, barrier methods and sterilization – is accessible. Practice, however, has resulted in a skewed method mix that relies heavily on abortion, traditional methods and hormonal contraceptives. Factors contributing to women’s limited choice in contraceptive methods are provider bias, combined with aggressive marketing by the pharmaceutical companies and an unreliable supply in the public sector.

Regulations governing the supply of FP/RH services, such as certification of private providers, private practice and clinics, *strongly support a growing private health sector.* As a result, individual and group private practice is on the rise albeit only in lucrative health services like dentistry, ophthalmology and curative medicine. The limited number of private gynecologist offer family planning as part of a larger portfolio of lucrative reproductive health services, such as RH diagnostics and treatment, abortion, etc. A few policies and practices that may constitute barriers to accessing FP/RH services and products merit further analysis. As noted below, in many instances an intervention changing existing practices might be more effective than a change in law or regulation. The first policy restriction – barrier to NGOs becoming FP/RH service providers – relates to the private sector. The other two affect FP/RH access in general.

Several inhibiting factors prevent NGOs from becoming service providers. Recently the government changed the laws governing NGOs activities so they can provide FP/RH clinical services. Although this change is significant, it is unlikely that many NGOs will take advantage of these changes in the near future due to multiple factors creating disincentives for NGOs: 1) NGOs are not permitted to charge for services or donated products, 2) there is limited international funding to support NGOs, and 3) NGOs have limited access to domestic capital to establish private practice. Further analysis is required to determine whether the

overall FP/RH marketplace would benefit from greater NGO role in service provision, and whether allowing NGOs to charge for services and products is feasible. A mechanism to help NGOs secure a steady funding base would also have to be identified.

Prescription norms may present a barrier to access, primarily for rural women who rely on Feldeshers for primary health care. Although Ob-Gyns can prescribe FP methods, most Feldeshers do not have a Gynecologist or Family Medicine Doctor, requiring a rural woman to travel to obtain FP counseling/services and to purchase a FP method. However, the reasons why rural women do not use FP methods are unclear. Does the prescription norm create a true barrier to access? Or is the lack sufficient information on FP's benefits the reason why rural women not demand FP services? Further analysis is therefore needed to determine whether changing the prescription norm is an appropriate intervention.

Adolescents face barriers in accessing FP information, products and services. According the Health Law, youth under 18 years require parental consent to receive such services. Actually practice, however, does not prevent adolescents from accessing FP services and information through MOH facilities. MOH providers interviewed by the assessment team did not require parental approval when youth asked for FP counseling and services. Most youth, however, do not spontaneously go to the MOH for their RH needs. NGOs for their part respect the law and restrict their activities to youth older than 18 years. Despite the abundant supply of condoms and other FP methods at kiosks and pharmacies, there is a widespread assumption that young people cannot afford them. Again, further research is required to determine whether changing the law is the appropriate "trigger" to address barriers to youth, or whether well-designed youth-friendly programs by NGOs might be more effective.

It is important to note that two key practices affect access to quality FP/RH products, services and information, but do not necessarily impact the private sector directly. There are 1) operational barriers to more efficient and equitable provision of FP/RH services and, 2) inadequate funding by the Ukrainian government allocated to the MOH National Reproductive Health Project (NRHP). These barriers, which would benefit the entire FP/RH sector, can only be addressed through major reforms that are beyond the scope of a private sector initiative.

2.2 Contraceptive product supply

The current range of modern contraceptive products available on the Ukrainian commercial market includes condoms, oral contraceptives, injectable contraceptives, and intra-uterine devices (IUD). Condoms are available in a variety of features (classic, lubricated, ribbed, studded, ultra-thin, ultra-strength, etc.) and at different price points (from UAH 2.00 to 9.89 for a pack of 3 condoms). Condoms are for the most part imported from Western Europe or Asia and distributed through pharmacies, grocery stores and kiosks. One Ukrainian company (LATEX) packages imported condoms locally and offers some of the lowest-priced brands. The range of brands and features decreases outside urban areas and is limited to a few low-price products in rural areas, as predicated by consumer demand and purchasing power.

A growing market for hormonal contraception

Oral contraceptives constitute a growing and dynamic segment of the contraceptive market. While condom brands are merely imported by local distributors and sold to wholesalers and retailers with limited advertising and promotional (A&P) support, hormonal contraceptive brands benefit from the marketing and financial capacity of pharmaceutical companies with a vested interest in the Ukrainian market. These companies include Organon (Netherlands), Schering (Germany), Richter Gedeon (Hungary), Pfizer (USA), and Yanssen Cilag (a subsidiary of Johnson & Johnson). This team focused on understanding the respective corporate strategies of these pharmaceutical companies as they relate to the country's future contraceptive security. Table 1 presents pharmaceutical companies that are active on the contraceptive market, their product portfolio, and their respective marketing strategies.

Table 1. Contraceptive Brands Sold in Ukraine

| Manufacturer | Schering | Organon | Richter Gedeon | Janssen Cilag | Pfizer |
|---------------------------|--|--|---|---|--|
| Product portfolio | Combined OCs: <i>Diane 35</i> <i>Jeanine</i> <i>Logest</i> <i>Microgynon</i> <i>Minisyston</i> <i>Orlon</i> <i>Triquilar</i> <i>Trisiston</i> <i>Yirina</i> IUD <i>NovaT</i> <i>Mirena (hormone releasing)</i> | Combined OCs: <i>Marvelon</i> <i>Mercilon</i> <i>Laurina</i> <i>Tri-merci</i> Progestin-only: <i>Exluton</i> IUD: <i>Multiload</i> Pending: <i>NuvaRing vaginal ring</i> | Combined OCs: <i>Lindinet</i> <i>Novynette</i> <i>Ovidon</i> <i>Regulon</i> <i>Rigevidon</i> Emergency Contraception <i>Postinor</i> | Combined OCs: <i>Cilest</i> Pending: <i>Ortho Evra</i> <i>Contraceptive patch</i> | Injectable: <i>Depo Provera</i> |
| Market standing | <i>Market leader</i> | <i>Market innovator</i> | <i>Leader in low-cost products</i> | <i>Minor player re-entering market</i> | <i>Only injectable manufacturer</i> |
| OC prices | <i>\$1.45 - \$10.50</i> | <i>\$5.50 - \$9.00</i> | <i>\$0.90 - \$5.00</i> | <i>N/A</i> | <i>N/A</i> |
| IUD prices | <i>\$5.00 - \$100.00</i> | <i>\$15.00 - \$20.00</i> | <i>N/A</i> | <i>N/A</i> | <i>N/A</i> |
| Other products | <i>N/A</i> | <i>Nuva-Ring: \$12.00</i> | <i>Postinor:</i> | <i>Patch: Undisclosed</i> | <i>Depo-Provera: \$6.00 - \$8.00</i> |
| Corporate strategy | <i>Offer wide range of products and prices</i> <i>Invest in high-margin brands</i> <i>Invest in provider relations</i> | <i>Innovate with new products</i> <i>Promote ethical provider relations</i> <i>Develop consumer relations</i> | <i>Invest in PR and provider education, reach out to youth</i> <i>Focus on mid-range, low-cost generic products</i> | <i>Discontinue OC brand</i> <i>Innovate with new products</i> | <i>Maintain monopoly</i> <i>Minimize investment</i> |

As a general trend, contraceptive manufacturers are adopting an innovation-driven approach to the Ukrainian market, concentrating on middle and upper class, educated consumers who demand safety, quality, and increased method choice. Schering's *Mirena*, a hormone-releasing IUD retailing for \$100, *NuvaRing*, a combined hormonal vaginal ring developed by Organon soon to be launched in Ukraine, and Janssen Cilag's combination contraceptive patch, which is pending registration, reflect a strategy of expansion through innovative, high-priced products. These companies are targeting the most dynamic consumer segment for hormonal contraception: young, upwardly mobile women living in urban areas. While this strategy does not imply that the availability of lower-priced products is being threatened, it suggests that communication and promotional investments by pharmaceutical companies focus almost exclusively on the most profitable products and consumer segments.

The size of the contraceptive market in Ukraine is estimated at about \$6 million CIF (sales of manufacturers to local wholesalers). Although it has been growing steadily, this market appears to be reaching a plateau. This, in marketing speak indicates a saturation of the supply side and calls for increased fighting for market share, and/or reaching out to potential new users. Efforts to broaden the market through the reduction of consumer prices appear to have failed: Schering reportedly experimented with a 70% reduction of the price of its lower-end brand Minisyston, and noticed no change in sales. At the higher end, the introduction of Yirina, a third generation OC, had a cannibalizing effect on other brands in the portfolio and failed to increase the market. As a result, the struggle for increased market share is taking place through the launching of innovative products and the concentration of efforts on the most profitable targets: at the consumer level, that would be young, urban-living middle and upper class women (especially students) and at the provider level, trusted doctors who are loyal to a company's brands.

The symbiosis between suppliers and service providers

Contraceptive manufacturers implement research and marketing activities through fully owned affiliates based in Kiev. These representative offices employ large teams of medical representatives (typically called detailers) who conduct regular visits of public and private providers in order to promote company products and provide technical support. These teams, which constitute the pharmaceutical industry's most important marketing tool and absorb a large part of its operating costs, have played a critical role in increasing provider confidence in hormonal contraception. It is estimated that pharmaceutical detailers cover 95% of gynecologists in the country. This level of attention, however, is rarely extended to general practitioners and family doctors.

The close collaboration between pharmaceutical companies and public sector health providers has been facilitated by a relatively open-minded attitude from the Ministry of Health (MOH) and medical associations. Pharmaceutical companies, for example, support continued education for health providers through conferences and workshops on specific topics (including contraception). Direct-to-consumer communication efforts, however, are limited by the prohibition of branded advertising for prescription drugs. Although registering OCs as over-the-counter (OTC) products can circumvent this law, there is limited interest among manufacturers in developing large-scale consumer campaigns. As a result, while providers have substantially benefited from public and private efforts to increase the use of modern contraception, potential users remain relatively uninformed about these methods.

Because the Ukrainian government is known to adopt a "hands-off" attitude towards the private sector, the pharmaceutical industry is in a large part, self-regulated. The tightening of

the market has led to a number of unethical practices (not limited to the contraceptive segment) that cause distortions in normal supply and demand patterns. For example, at least one pharmaceutical company is reportedly paying doctors to prescribe its products. There is also widespread complaining that providers demand free samples in return for favoring a company's products, and then sell these samples to their patients. These and other unethical practices are of great concern to the Health Care Committee of the European Business Association, an industry group working on improving health regulations and marketing ethics in Ukraine.

A well-developed commercial distribution

Commercial pharmaceutical suppliers sell a wide range of mostly low-dose oral contraceptives, including so-called third generation pills, a progestin-only pill (Organon's *Exluton*) and an emergency contraception pill (Richter Gideon's *Postinor*). These products are distributed through a vast network of wholesalers and retailers whose potential reach extends to all regions of Ukraine, including rural areas. In the absence of distribution surveys or industry-generated information (such as the list and location of registered pharmacies), it is impossible to estimate actual distribution coverage for contraceptives, which are often re-sold to several wholesalers before they reach retail outlets. Although pharmaceutical distributors typically claim to carry a wide range of products and serve a wide geographic area, there are reasons to believe that the range of available contraceptives diminishes drastically outside urban areas. There is nevertheless a strong belief among commercial suppliers that most Ukrainian women can access contraceptives if they want them, and that limited product availability simply reflects a lack of demand and a preference for low-cost brands. The proliferation of pharmacies and wholesalers indeed supports this theory. In areas where few pharmacies are established (as in villages with less than 5,000 inhabitants), rural Feldeshers are known to maintain a stock of essential drugs (including contraceptives when requested) that they order from the nearest pharmaceutical outlet.

An industry in transformation

The continued availability of contraceptives is subject to the overall availability of pharmaceutical drugs in Ukraine. This market has experienced an explosive increase in the number of pharmaceutical wholesalers and retailers in the past decade that has produced high competition and lower margins (limited to 10% by law but typically as low as 3%). This sector is currently undergoing a consolidation phase characterized by the closing of wholesalers. According to the representative of a prominent pharmaceutical chain in Kiev, 260 wholesalers out of 300 have closed their operations in the past year. This consolidation, however, is welcomed by the industry because it favors the creation of larger, well-financed wholesale groups with broader reach. The closing of unprofitable wholesalers is unlikely to affect product availability, and the number of pharmaceutical retail outlets is actually growing. The number of pharmacies has increased from about 6,000 a few years ago to about 15,000 today. Pharmaceutical sales remain a highly profitable business in Ukraine, fueled by a growing consumer demand for products that must be met almost exclusively by the private sector.

A lack of market research data

In spite of the proliferation of research firms in Ukraine, it is difficult to access reliable data about contraceptive product sales, market share, consumer trends and distribution coverage. One company, Business Credit, currently collects comprehensive sales and

distribution data through periodic surveys of pharmaceutical outlets. This research firm, however, does not sample condoms, and does not monitor products sold directly by wholesalers to consumers or providers (as is often the case for IUDs). In addition, the accuracy of available pharmaceutical sales data has been questioned by some of the client pharmaceutical firms.

Consumer research relating to the contraceptive market also appears to be scant. The absence of a recent national reproductive health survey creates an information vacuum that is not compensated by private sector market research. Pharmaceutical company affiliates do not usually invest in quantitative studies but rather in qualitative research such as focus groups and in-depth interviews. More resources are invested in provider research, including surveys of up to 100,000 physicians at a time. This information however is very costly and strictly proprietary. To date there has been no spontaneous effort among pharmaceutical companies to join forces and fund research that could benefit the entire industry.

A dearth or consumer-directed information

If health providers have benefited from training and communication efforts from the MOH and the pharmaceutical industry, the general public is seldom the focus of information and behavior change campaigns, which in turn contributes to the sluggish demand for contraceptives. The majority of persons interviewed by the assessment team both in the private and public sectors identified the lack of public information as the priority issue to be addressed for contraceptive prevalence to increase in a significant fashion. Several inhibiting factors appear to be at work: limited public funding affects the ability of the MOH to communicate with potential users; the absence of consumer research makes it difficult to design effective programs; real or self-imposed limitations on brand advertising discourage manufacturers from communicating with consumers; and legal restrictions on messages targeted at minors hinder public education campaigns. Beyond its impact on product demand (and indirectly, the growth of contraceptive supply), the lack of programs directed at high-risk groups, especially youth, constitutes a public health concern.

2.3 Reproductive Health and Family Planning Services

Traditional reliance on the public sector

The public sector is clearly the dominant provider of FP/RH services. The Ministry of Health offers FP/RH services and counseling through multiple facilities under their countrywide service delivery network. Facilities include maternity centers, outpatient clinics, women's consultation centers, RH/FP centers, and Family Medicine centers, and the MOH has trained Ob-Gyns and Family Medicine doctors in the provision of FP/RH services and counseling. The challenges associated with public sector provision of FP services are well documented in other reports (see PopTech 2003 Assessment, Deliver Project Assessment 2004, POLICY Project Operational Policy Barriers Analysis 2003). The following is a discussion of public sector practices and behaviors that affect contraceptive security.

The fluid and close relationship between pharmaceutical companies and public sector physicians influences prescription practices and therefore contraceptive choices. Public providers displayed a preference for oral contraceptives, reflecting intensive marketing

activity by pharmaceutical companies, as well as provider training efforts in the public sector. All public sector providers interviewed consistently said that they believe older generation and generic hormonal contraceptives are “inferior” products and therefore prescribe only expensive, so-called 3rd generation pills. This may present a problem if a large percentage of women cannot afford the newest pills. Public providers also like to prescribe oral contraceptives for a host of RH problems. For example, several physicians use *Regulon* -a product marketed by Richter Gedeon- to regulate a woman’s menstrual cycle after an abortion. In contrast, these providers generally reported a lack of interest in prescribing injectable contraceptives, which have the reputation of causing undesirable side effects. This attitude is reflected in turn in the market for *Depo Provera*, considered negligible in comparison with the OC market. According to Pfizer, the only manufacturer of injectable contraceptives operating in Ukraine, only a small niche of providers prescribes the product for essentially therapeutic indications.

There is minimal interest among public providers in promoting the use of IUDs as a method. According to many informants, the use of IUDs has decreased dramatically in the last 5 years (some reported it to be as low as 10% of prevalence). Explanations vary as to why IUDs use is declining, but some providers may be applying overly stringent eligibility criteria for IUDs that are not evidence-based. Because of this, abortions may actually be more accessible to women than IUDs. Public health providers are also known to prescribe excessive testing that is not medically indicated, according to international norms, and represent an additional cost for users.

By all accounts, there is little supervision of the relationship between public sector providers and the pharmaceutical companies. Many of the pharmaceutical companies’ representatives stated they have complete and unrestricted access to public sector providers. Because the MOH has limited funds, it must rely heavily on the pharmaceutical companies for promotional materials and contraceptive technological updates, and may not be able to counterbalance their influence on doctors’ prescribing practices. Although the content of promotional material must be theoretically approved by the MOH, this regulation is not enforced. The MOH has also refrained from intervening amidst persistent allegations of unethical behaviors by pharmaceutical companies and doctors.

Despite the constitutional right to free medical services in the public sector, almost all patients find themselves having to purchase drugs and supplies from pharmacies, as well as make direct, informal payments to public sector health providers. Facilitated by the MOH interpretation of Article 49 allowing facilities to charge patients for “products” (defined as medicines and medical supplies such as syringes, bandages, etc.), informal payment have created a “shadow” private market that is highly advantageous to providers. Prices are commensurate with a provider’s professional degree and reputation, and therefore vary from provider to provider, and facility to facility. Providers are hesitant to discuss prices directly with their patients or anyone else, so those are typically communicated through word-of-mouth. It is unclear whether the existence of informal payments is preventing low-income clients from seeking FP services. The most detrimental impact of this shadow market, however, may be that it discourages public sector providers from setting up their own practice, which always involved high costs and considerable risk.

The informal payment structure is so entrenched that the provider community is likely to oppose strong resistance to any initiatives to changes the status quo (see Operational Policy Barriers Study for further details). On the positive side, the informal payment system has made clients accustomed to paying for services. Among the hardest transitions from a

universally free health care to fee for service system is getting clients used to the notion of having to pay for services and products. Ukraine does not face this barrier. Except for vulnerable population groups, everyone pays for something for medical services, thereby creating an informal private practice -fee-for-service- within the public sector.

An emerging private health sector with limited FP/RH focus.

While the number of providers working in private sector clinics on a part-time of full-time basis appears to be on the increase, these providers tend to concentrate on profitable services such as dentistry, ophthalmology, oncology, diagnostics, outpatient surgery, and gynecology. This pattern in the private health care follows past trends in other Eastern European countries where liberalization policies attempted to foster private sector growth after the fall of communism. Family planning and other reproductive health services eventually followed, and the market place matured. With a dominant public sector offering “free” family planning services, there is simply no economic incentive at the moment for private providers to offer preventive services such as family planning.

Consequently, existing private providers working in the RH area focus on the most profitable gynecological services, such as ultra-sound and other gynecological tests, abortion, hormonal replacement therapy, and infertility treatment. A quick review of the prices charged for service suggested that only higher income groups could be expected to afford private health care. In the three sites visited (Isida, Medikom and Boris clinics) 50 to 75% of patients, however, carried employer-paid private medical insurance that helped defray the cost of services and some drugs. Private health insurance schemes tend to cover almost all gynecological services, including FP consultations, hormonal products used for RH treatment (not contraception), IUD insertions (excluding product costs), and abortions.

Private provider attitudes toward reproductive health vary greatly but at least one prominent gynecologist reported attending international conferences on contraceptive technology and stocking IUD brands not available in Ukrainian pharmacies. Private providers exhibit the same attitudes and practices toward contraception as public sector providers, with a clear preference for oral contraceptives, and a limited interest in prescribing injectable contraceptives or IUDs to their patients.

Limited potential for the NGO sector.

With the bulk of services currently provided by public sector facilities, and the concentration of product supply in the commercial sector, there is limited room left for non-profit organizations to play a significant role in reproductive health. Because of legal restrictions on their ability to provide products and services, NGOs tend to focus exclusively on advocacy and education. Some NGOs are essentially professional associations pursuing a specific agenda or para-statal organizations created to circumvent rigid regulations of provider activities in the public sector. There is evidence, however, that some NGOs, particularly those belonging to the Reproductive Health Network (RHN) have played a key role in changing provider attitudes and lobbying for improvements in the quality of services in the public sector. Although a recent law has made it possible for NGOs to provide services and products to patients, few seem to have the human, technical and structural capacity to become service providers. Moreover, NGOs are not permitted to charge for services and products, which limits their ability to recover costs. NGOs, however, can play a critical role in addressing the persistent lack of knowledge about contraception among Ukrainian women through direct-to-user communication campaigns.

2.4 Public vs. Private Sector Roles

A “double” monopoly of FP/RH services and product supply

Table 2 demonstrates that the supply of FP/RH products is essentially dominated by the commercial sector through private pharmacies whereas the supply of FP/RH services is ensured by the public sector. NGOs are increasingly taking a lead role in activities not monopolized by the public or private sector, such as information campaigns directed at consumers.

Table 2. Overview of Private/Public Mix

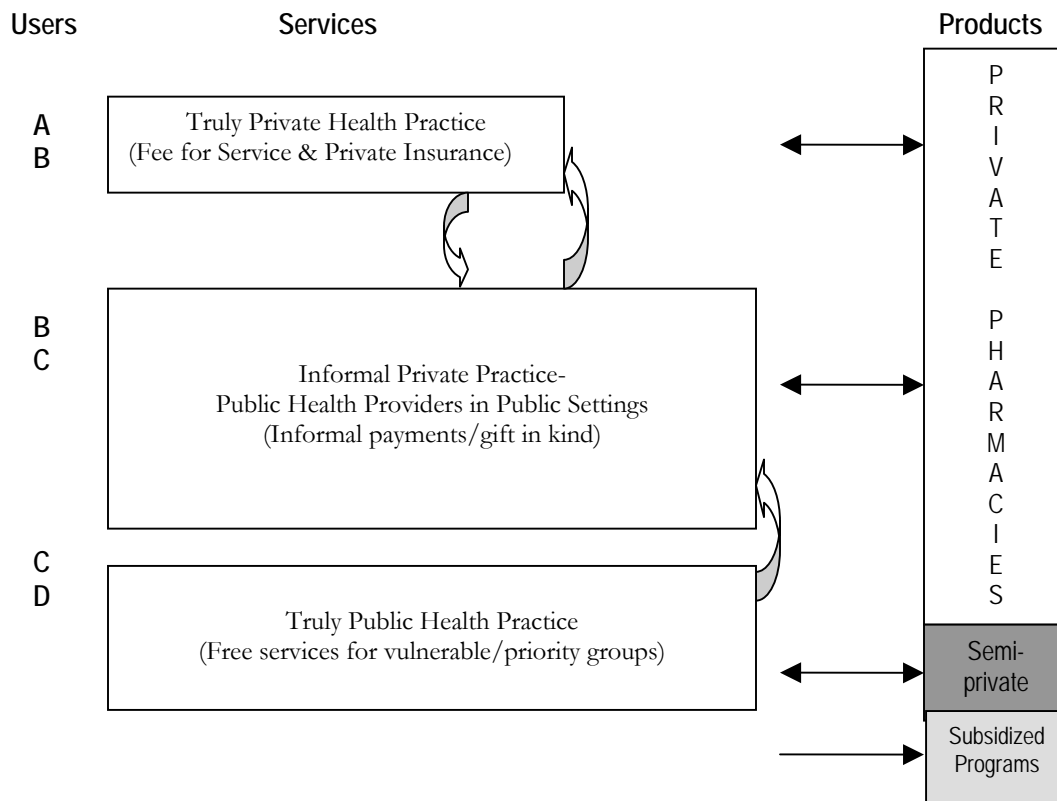
| | Supply | Demand |
|----------|--|--|
| Services | Public <ul style="list-style-type: none"> ▪ Ambulatory Clinics (w/Family Medicine MDs) ▪ FP Centers @ Women's Health Centers with OB/Gyns ▪ Maternity Hospitals- limited post-partum care | <ul style="list-style-type: none"> ▪ NGOs through IEC, counseling and referrals |
| Products | Private <ul style="list-style-type: none"> ▪ Pharma Companies ▪ Wholesalers ▪ Private and Semi-private pharmacies | <ul style="list-style-type: none"> ▪ NGOs through IEC materials and activities ▪ Public Providers through counseling & prescriptions ▪ Pharma Cos through promotional materials and detailing |

There are very few incentives for an increased provision of reproductive health services through the “pure” private sector. As Figure 1 demonstrates, the combined advantage of the large volume of patients using public sector facilities and the existence of informal payments to providers practicing in these facilities makes private practice attractive only for providers catering to a small, wealthy clientele (A, B). Until steps are taken to eliminate informal payments in the public sector, private sector service provision will not increase and most couples will continue to seek FP/RH services at public clinics. The few private sector doctors with a progressive approach toward contraception are more likely to play a role as opinion leaders than as service providers for average Ukrainians. Moreover, the bulk of patients with unmet health needs are likely to be found in the lower-income and rural segments of the population who cannot at this time access private sector clinics and must be served by the MOH.

Public/private relationship in the supply of products

Figure 1 illustrates the unique relationship that has developed between public/private sectors with respect to supply of FH/RH products. The attitudes and practices of public sector providers, who represent the largest body of service providers, have much influence on the demand for contraceptive methods and in turn the availability of these methods on the commercial market. The absence of consistent product supply in public clinics has resulted in a virtual supply monopoly in the private sector, and public sector providers and private sector suppliers find themselves in a mutually dependent relationship that has had both positive and negative influences on the availability of contraceptive products. On the positive side is a close collaboration between pharmaceutical companies and public sector providers that has led to a substantial change in attitude towards hormonal contraception. On the negative side is an absence of a program dedicated to those unable to afford or access commercial products, and ethical questions regarding the objectivity of the product information provided to patients. While services remain relatively easy to access and (at least in principle but not in practice) free of charge, there is some concern that even the cheapest condom or OC brands might be too expensive for low-income Ukrainians.

Figure 1. Overview of Supply Sources and Users



3. Conclusions

The analysis of the policy environment, market conditions and medical practices points to the following key conclusions:

There does not seem to be a pressing contraceptive security problem in Ukraine where products are concerned. Although research is lacking that could determine with certainty whether all consumers have access to affordable products, there is no obvious supply crisis in Ukraine. Unlike other countries where most women obtain their contraceptive products from public sector or NGO outlets, Ukraine has a well-developed commercial market that caters to average consumers and not just the elite. While pharmaceutical companies tend to invest marketing resources in high-margin products, they are careful to keep low-cost brands in their portfolio. The sustained presence of *Rigevidon* (Richter Gideon), *Marvelon* (Organon) or *Microgynon* (Schering), the most affordable OCs on the market, does not appear to be threatened as long as there is demand for these products. In addition, wholesalers that depend on a high-volume business are careful to keep a wide and diversified portfolio (typically several thousand products) in order to maximize revenue.

The lack of research data, however, leaves some contraceptive security questions unanswered. The extent to which consumers located outside urban areas have easy access to contraceptive products can only be determined through quantitative consumer or distribution surveys, which are not currently available in Ukraine. Besides people living in rural areas, young people and the urban poor may not be able to afford commercial contraceptive products. Only quantitative research, however, can provide an estimate of the size of the under-served population. The upcoming Willingness To Pay survey conducted by the Policy Project, however, is expected to shed some light on the affordability issue but more segmentation-type research may be needed.

Widespread access to products and services does not extend to accurate and reliable information about FP/RH. Public and private sector providers, as well as OC manufacturers, agree that lack of information and education among potential users is the biggest barrier to increased use of modern methods. Information and education are needed to turn unmet need into potential demand and eventually leads to increased use of modern methods. Ukrainian men and women may have ample access to products and services but their need for basic information and counseling is not adequately met by the public, private or NGO sector.

The current method mix is driven by industry pressure and provider attitudes rather than public health goals. Contraceptive security implies a choice of methods and counseling that is based on patients' needs and preferences. While the current method mix reflects a reduction of the use of abortion and a higher reliance on hormonal methods, the difficulties associated with obtaining an IUD and the limited availability of injectables reflect a trend toward a limitation of options for Ukrainian women. This trend is likely the result of pervasive misconceptions about both methods, as well as the industry-driven focus on oral contraceptives.

Efforts to bolster the development of private sector service providers are unwarranted at the present time. Because the public sector reaches deep into the various Ukrainian oblasts, services channeled through this sector are likely to reach all population groups and they are more likely to be affordable than those channeled through the burgeoning private sector. Likewise, the national product supply is best served by the commercial distribution, which is both more efficient and financially sustainable than distribution programs channeled through public sector outlets. As a result, policy efforts should focus on correcting problems (such as provider education or ethical issues surrounding pharmaceutical activities), and designing a national contraceptive security strategy that makes the most of the capabilities of each sector (public, private and NGO).

4. Key Recommendations

Based on the findings and conclusions of the market analysis in Ukraine, the PSP-*One* Team offers the following recommendations:

Avoid supply-side activities that could have a counterproductive effect on the commercial contraceptive market

It would be tempting to increase contraceptive supply in Ukraine by introducing free or subsidized products on the market, through either public or private sector channels. Doing so without considerable investments in targeted IEC activities, however, may have the effect of competing with commercial suppliers for existing consumers. When such competition takes place, a typical reaction from these suppliers is to limit their product portfolio to a few high-price brands targeted at a small, upper income user group. In the long run, this may lead to a rarified commercial supply that no longer serves the needs of average consumers.

Identify priority groups for demand-side activities

Despite the lack of research data, it is possible to infer from interviews of contraceptive suppliers and service providers that users of OCs tend to be young, middle class urban women, condom users young urban men, and IUD users older, low to middle income women. Pharmaceutical companies have identified female university students as their fastest-growing customer segment and are investing the bulk of their resources on this core groups. Students are most likely to have reservations about abortion, harbor fewer misconceptions about hormonal contraceptives, and have easy access to counseling through campus clinics. Other key target groups for growing the contraceptive market are post-partum women and post-abortion patients. As previously noted in the 2003 POPTECH report, this group represents a “missed opportunity”, because women who deliver or abort are most likely to need FP counseling, yet rarely receive it. Finally, adolescents should be considered a priority group because they are at high-risk of STIs and repeat abortions. This group, however, is less likely to adopt contraception than older women and may require intensive communication efforts.

Work with pharmaceutical manufacturers that have an interest in the contraceptive market

The efforts of pharmaceutical companies to market hormonal contraceptives to providers can be supported and expanded. A social marketing intervention based on a partnership with one or several manufacturers could have a substantial impact on both the demand and supply sides of the market. When market conditions are right, as is the case in Ukraine, manufacturers can be persuaded to increase their investment in distribution and promotional activities in response to large-scale campaigns directed at consumers and other supportive activities. Should research demonstrate that a large percentage of the population is unable to afford commercial contraceptives; manufacturers may agree to decrease the price of some of their brands. It is important to recognize, however, that partnerships with commercial providers work best when they are targeted at the core consumer group (in the case of Ukraine, young, middle class urban women). For high-risk and low-income groups, activities channeled through the public sector or NGOs are more appropriate.

Address gaps in knowledge and misconceptions among service providers

It is necessary to renew and sustain training efforts in the public sector in order to increase the use of modern methods. Providers have substantial influence on the method mix available in Ukraine through their counseling and prescription practices. There is some evidence, however, that intensive marketing activities conducted by some pharmaceutical companies are skewing provider preferences toward OCs, particularly more expensive third-generation pills. Because access to other methods such as IUDs and injectables is a condition for contraceptive security, it is important to ensure that the information and training provided to doctors does not emanate exclusively from pharmaceutical companies. Consequently, we recommend renewed training in contraceptive technology, possibly conducted by NGOs that enjoy a close relationship with service providers, such as the Ukraine Family Planning Association. Activities involving private sector providers are not recommended at this time as these providers only cater to a small percentage of the Ukrainian population.

Encourage improved linkages between product suppliers and service providers

Potential users of family planning methods are typically prescribed a brand of contraceptives that they must then purchase in a pharmacy. This is often the only link between suppliers and providers. Unfortunately, the relationship between these two groups has been marred by abuses, such as the re-selling of samples by providers, or the bribing of doctors by pharmaceutical companies. One company, however, is undertaking a new initiative (previously tested in Russia) that consists of providing doctors with 1) one free sample per patient 2) a coupon for three months worth of free products for each patient 3) a toll-free number where patients can be referred to a participating pharmacy. This system allows for better linkages between doctors, pharmacies and consumers, more efficient sampling programs, and improved monitoring of both patient and doctor behavior patterns.

Identify under-served groups and address their contraceptive security needs

The private sector cannot be expected to reach all consumers if it is not profitable to do so. It remains, however, essential to meet the needs of all potential users in Ukraine to achieve contraceptive security. Because the industry and MOH generate very little consumer research, it was not possible to obtain a definite estimate of the proportion of the population that can afford commercial products, though physical access seems adequate for the majority of users. We do not eliminate, therefore, the possibility of a dedicated program that could make free or subsidized products available to specific groups, particularly adolescents, rural and low-income women. The distribution of these products, however, should take place in the context of a targeted strategy and be supported by effective logistical and monitoring systems. Technical assistance to the MOH will likely be needed to minimize leakages in the commercial distribution and target commodities to those who need them the most.

5. Proposed Strategy to Increase Private Sector Participation in Contraceptive Security and RH/FP Goals

The private sector is already an important player in the RH/FP arena. In addition to their contribution to contraceptive security through sustained product supply, private sector efforts have been a factor in achieving broader public health goals, such as increases in contraceptive prevalence and the reduction of abortion rates. This contribution can be maximized through a dual strategy of public/private partnerships, and public sector policies that facilitate and complement the activities of the private sector. Below is a presentation of a strategy to strengthen private sector's role in the RH/FP marketplace. Figure 2 provides a visual overview of the PSP-*One* proposal.

5.1 Partnership activities between public and private sector

A sustained effort to communicate the benefits, effectiveness and safety of contraceptive products (especially hormonal methods) is necessary to achieve substantial growth in the use of modern methods. Although pharmaceutical companies have demonstrated a willingness to invest in this market, their focus is likely to remain on service providers. To complement these efforts, we recommend implementing a large-scale behavior change initiative targeted at specific target groups among the most likely adopters of modern methods. The goals of this intervention would be to reinforce the efforts of the private sector in growing its core consumer groups (young, urban women, especially the student population), address the unmet needs of post-partum and post-abortion patients, and reach out to high-risk groups such as adolescents.

Partnerships with commercial manufacturers can take different forms but typically include a commitment by both parties (the public and private entity) to invest in activities that can substantially grow the contraceptive market. Such activities may include:

- Designing and implementing consumer research, mass media advertising, product sampling, and public relations campaigns
- Increasing distribution coverage for contraceptive products in under-served areas
- Ensuring the wide availability of affordable products (the upcoming Willingness to Pay Survey conducted by the POLICY project will help determine whether a reduction in price is needed in order to reach lower-income users)
- Increasing provider outreach activities by pharmaceutical companies, including high-profile events public relations campaigns, expanded pharmaceutical detailing, and controlled product sampling programs

- Supporting and expanding the activities of NGOs with technical expertise and experience in dealing with target groups, as well as those involved in advocacy and provider training
- Training providers in the special needs of adolescents and supporting the creation of youth-friendly counseling programs in collaboration with NGOs
- Coordinating partnership activities with public sector programs (see next section)

5.2 Policy activities to promote public/private partnerships

The public sector plays a critical role in the well being of the private sector. We propose working closely with the MOH to facilitate and complement private sector initiatives while at the same time, achieving important public health goals such contraceptive security, increases in the use of modern contraceptive methods and a reduction in abortion rates.

The focus of the second strategy should be to assist the MOH in taking a leadership and oversight roles in partnerships between public, private, and NGOs engaged in FP/RH activities. A possible strategy would be to help the MOH formalize the partnership between these stakeholders by drafting a memorandum of understanding (MOU), facilitating regular coordinating meetings and developing a work plan of activities that conform to public and private agendas. As a group, the public and private sector partners could develop and implement a National Contraceptive Security Strategy as their first initiative together.

Targeting subsidized commodities is a critical strategy to ensure that under-served populations have access to FP information and modern methods. Under-served potential users include several population groups: those who want to adopt modern methods but have limited access to commercial pharmacies; those with limited access to information and counseling services, and those who cannot afford commercial contraceptive brands. In addition, individuals at high-risk of unwanted pregnancies, repeat abortions and/or STI infections and HIV/AIDS should be considered under-served because they lack the information and motivation to adopt safe behaviors. It is important, however that the MOH implement this subsidized commodity program with care so to not harm the vibrant commercial supply of FP/RH products. Proposed activities include:

- Conducting a market segmentation analysis to identify under-served groups (such as low-income peri-urban and rural populations, youth, etc)
- Identifying geographic areas where demand for contraceptive products is not satisfied because of limited access to commercial products (using consumer research, a distribution survey or other assessment tools)
- Identifying socio-economic groups with unmet demand for contraceptive products (using the upcoming willingness to pay survey)
- Designing a commodities distribution program to be implemented by select public outlets

- Providing technical assistance to the MOH in targeting commodities to priority groups
- Coordinating with private sector initiatives to develop and implement a BCC program targeted at priority groups

A final area where the public sector can play a lead role is in improving the attitudes and practices of services providers and encouraging greater use of modern methods. Given the MOH's limited resources, both pharmaceutical companies and NGOs can assist in carrying out the proposed activities. Greater MOH involvement and direction in these activities, however, will ensure a more balanced perspective on contraceptive methods. Activities may include:

- Supporting large scale contraceptive technology updates targeting MOH gynecologists, obstetricians and family medicine doctors
- Encouraging providers to offer a more balanced method mix through better prescribing practices
- Training providers to manage the side effects of hormonal methods, particularly injectable contraceptives

Annex A: Key Informants

| Sector | Organization | Individual/Title |
|------------------------------|---|---|
| Donor Sector | USAID | Tim Clary, Senior Advisor for HIV/AIDS, Infectious Diseases and Reproductive Health |
| Public Sector | Ministry of Health of Ukraine | Nadiya Zhylka, Deputy Head Maternity and Childhood Health Care Department Mikola Georgiovitch, Deputy Chief of Legal Administration Vladimir Golovakov, Deputy Head Anesthesiologist, Zhitomir Oblast Grygory Lysenko, Head of the Family Medicine Department Kiev Medical Academy of Postgraduate Education. Inna Demchenko, First Deputy Director, Government Service of Medicines and Medical Supplies Boris Ventskiivskiy, Head of Department of Obstetrics and Gynecology No. 1 |
| Private Medical Providers | ISIDA Clinic Medikom Clinic Boris Clinic | Viktor Viktorovith, IVF Department Deputy Volodymyr Bannikov, Obstetrician-Gynecologist |
| Pharmaceutical Manufacturers | Azko Nobel (Organon) Schering Richter Gedeon Pfizer HCP Corporation Yanssen Cilag | Konstantin Zubovskiy, Managing Director, Russia, Ukraine and Kazakhstan Roman Bishovets, Head of Representative Office in Ukraine Vladimir Redko, Business Unit Director Dr. Victoria Timoschenko, PR Manager Mariya Zimovets, Business Development Manager Janos Szabo, Head of Representative Office Alexander Gorbenko, Product Manager Andrei Obrizan, Product Manager Ibor Nykyforchyn, Marketing Manager Alexander Melnik. Marketing Director |

| | | |
|------------------------------------|--|--|
| Pharmaceutical distributors | VVS Medical Supply Protek-Pharma Nevid Pharmacy Chain | Elena Andrushchenko, Business Manager Tetyana Marenich Mikolaivna, Marketing Director Elena Ivanova |
| Research Firms | Masmi Rating Business Credit Co. | Stanislav Chiglintsev, Director Andrey Borovskiy, Director Vladiimir Bogdan, Research Director Dr. Ludmila Sassina, Marketing Director |
| NGOs and Associations | Association of OB/GYN Ukraine Pharmacists Association Association of family Medicine | Boris Ventskivskiy, President Grygoriy Lysenko, President |
| | Ukrainian Family Planning Association European Business Association Woman's Health and Family Planning Women in Ukraine | Irina Vovk, Chief Specialist Emilia Nepochatova, Kiev branch Alexander Markov, Executive Director, Health Care Committee Galina Maistruk, Chief of Board Tatyana Dolishna, Chief Magazine Editor |
| USAID Contractors | The Futures Group JSI Mother and Infant Health Project | Andriy Huk, Country Director Helene Lefevre-Cholay, Chief of Party |

Annex B: Legal/Regulatory Assessment of Market Conditions for Private Sector Provision of FH/RH products & Services

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
|---|--|---|--|
| Regulations that govern Contraceptive Options | | | |
| Contraception Choice (Availability of Specific Methods) | <p>There is no legislation that limits the use of certain kinds of contraceptives.</p> <p>Article 49 allows a woman/man to choose sterilization by voluntary agreement and can have the procedure performed in an accredited medical institution (including a private sector as demonstrated by Medicum clinics). A 1994 ministerial order approved medical indications for voluntary surgical sterilization for women and men.</p> <p>There are restrictions on who may receive FP methods; in particular adolescents. According to Article 43 of the Health Legislation, OCs is regarded as a medical intervention. As such, a medical intervention requires the informed consent of the patient. If the patient is under 18 years of age, they require parental and/or legal guardian approval. This restriction, however, does not apply to condoms and other barrier methods.</p> | <p>Ministry of Health: Article 57 of the Fundamentals of Health Care; Norms and Standards</p> <p>Fundamentals of Health Legislation, Article 43</p> | <p>In principle, every modern method –pills, IUDs, injectables, barrier methods and sterilization – is accessible. Provider bias, combined with aggressive marketing by the pharmaceutical companies, has resulted in a skewed method mix. Historically, Ukraine providers steered women away from older generation of OCs and women used IUDs. Today, providers are more comfortable with newer generation of OCs and more women are using the pill. Also, IUDs are on the decline. Sterilization, used occasionally, is rarely discussed by providers or patients despite the liberal normative provisions governing sterilization.</p> <p>According to the Health Code, adolescents (youth under 18) cannot access to FP information, products and services without parental consent. NGOs are the primary source of FP info for adolescents. These NGOs have applied this restriction the provision of FP information and counseling, and restrict their materials and activities to older young adults. However, they acknowledge there is great need among younger adolescents (13 to 18 years). It is interesting to note that the MOH providers interviewed do not require parental consent to provide FP info and services. The problem is MOH is not the “preferred” source of FP info and services by adolescents and they do not actively go MOH facilities.</p> |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
|--|---|---|--|
| Regulations that govern Contraceptive Options (continued) | | | |
| Prescription and dispensing | <p>According to an MOH Ministerial Order, all pharmaceutical contraceptives require a prescription from an Obstetrician or Gynecologists.</p> <p>Businesses and individuals can sell pharmaceuticals with a special permit. Those who have appropriate training and can meet certain qualifications and education requirements are eligible to sell registered pharmaceuticals at the retail level. Permit costs are minimal (approximately \$10 for an individual and \$50 for a business). The permit is issued within 30 days.</p> <p>There are no restrictions on who can dispense condoms.</p> | <p>Ministry of Health:</p> <ul style="list-style-type: none"> ▪ Ministerial Order #233, Lists of Pharmaceuticals Registered in Ukraine, '97 ▪ Article 19 of the Law on Pharmaceuticals and Rules of Retail Pharmaceutical Sales: Ministerial Order #447, '97 ▪ Ministerial Order #1020, Procedure of Licensing Entrepreneurial Activities, '98 | <p>The prescription norm <i>may</i> present a barrier to access, primarily for rural women who rely on Feldeshers for primary health care. Although Ob-Gyns can prescribe FP methods, gynecologists are the principle health care providers of FP/RH and the ones most likely to prescribe a FP method. Increasingly Family Medicine Doctors also prescribe contraceptive methods and insert IUDs. However, Feldeshers often do not have a Gynecologist or Family Medicine Doctor, requiring a rural woman to travel to obtain FP counseling and services, and to purchase a FP method. The reasons why rural women do not use FP methods are unclear. Does the norm on prescriptions create a true barrier to access? Or is the reason why rural women not use FP methods/services because they lack sufficient information on and are unaware of FP's benefits?</p> <p>The laws and norms are supportive of individuals and businesses that wish to sell pharmaceuticals such as contraceptives given the robust number of kiosks, pharmacies and other outlets offering contraceptives.</p> |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
|--|--|---|--|
| Regulations that govern Contraceptive Options (continued) | | | |
| Product Approval; Licensing; Registrations | Registration is required for both pharmaceuticals (pills, injectables, foams, jellies, sponges, etc.) and barrier methods (IUDs, condoms, diaphragms, etc). Article 9 of Law of Pharmaceuticals states that all pharmaceuticals must conform to the procedures outlined in Cabinet of Ministers Resolutions #569: Procedure to Register and Re-register Pharmaceuticals. Oral contraceptives are registered as medicinal agents. IUDs, condoms and other barrier methods are registered as Medical Technologies. | <p>Ministry of Health: State Registrar of Pharmaceuticals, Pharmaceutical Registration Bureau, Pharmacological and Pharmacopoeias Committees, Dept. Control over the Quality of Medicines & Pharmaceuticals (Local FDA equivalent), New Medical Technologies Committee</p> <ul style="list-style-type: none"> ▪ '98 Law of Ukraine on Pharmaceuticals ▪ Cabinet of Ministers Resolutions #569: Procedure to Register and Re-register Pharmaceuticals ▪ Ministerial Order #74, Regulations of State Registry of Medical Technologies Products | <p>Pharmaceutical Registration Bureau registers any product based on an application submitted by the manufacturer. The Bureau reviews each application within a month. However, this time period does not include any specialized assessments (including clinical trials). As a rule, clinical trials are not carried out when an internationally acknowledged certificate exists for the product. Biological and medical trials are conducted in almost every case. Registration fee for any pharmaceutical is 1,000 Euros for each therapeutic form and 100 Euros for each subsequent dosage. This fee does not include additional cost for specialized assessments, which can be considerable. Registration process is shorter and requires a smaller fee.</p> <p>IUDs, condoms and other barrier methods also must be registered through the New Medical Technologies Committee.</p> <p>According to the Pharmaceutical Manufacturers interviewed, the registration process or fee appeared to be excessive or cumbersome.</p> |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
|---|---|---|--|
| Regulations that govern FP/RH Providers | | | |
| Certification of Private Providers/Private Practice/Clinics | <p>Private practice is legal with a license. The rules for issuing licenses for private medical practice, like licenses for retail sales of pharmaceutical, is regulated by a Cabinet of Minister Resolution form MOH and MOE.</p> <p>The Cabinet of Ministers also regulates the state accreditation for all –public and private- health facilities. All health facilities are subject to accreditation every three years.</p> | <p>Ministry of Health and Ministry of Economics: License Chambers</p> <ul style="list-style-type: none"> ▪ Cabinet of Minister Resolution #1020 on Licensing Entrepreneurial Activities, '98. ▪ Cabinet of Minister Resolution #765, The Procedure of State Accreditation of Health Care Facilities, '97. | <p>Private practice –both individual and group practice- is on the rise. This trend follows similar trends in other Eastern European countries that have liberalized medical practices: initially private practices are in dentistry, ophthalmology and preventive medicine because they are the most lucrative medical services. There are very few Ob-Gyns who offer FP/RH services. There are some restrictions on private Ob-Gyns. They are not permitted to provide follow-up care for pregnant women, treat complications during pregnancy or perform surgical interventions (including abortions) unless they are performed at an accredited state-owned medical institution.</p> |
| Tax and Import Policies | | | |
| Sales/Value Added Taxes | <p>According to Article 5 of the Law on Value-Added Tax, pharmaceuticals and medicinal goods in Ukraine are exempt from VATs.</p> <p>Private health care services delivered by licensed health care institutions are also exempt from VAT. Another Resolution further clarified this provision stating specifically that FP/RH services are exempt from VAT.</p> | <p>Finance Ministry</p> <ul style="list-style-type: none"> ▪ Law on Value Added Tax, '97 ▪ Cabinet of Ministers Resolutions #1602 | <p>These favorable terms exempting pharmaceuticals and medical goods – including condoms - from VAT do not create a disincentive. Also, VAT exemption for private sector medical services, particularly FP/RH services, will help stimulate the eventual expansion into this health area.</p> |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
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| Regulations that govern FP/RH Providers | <p>Article 7 of the Law of Pharmaceuticals permits the importation of contraceptives in Ukraine if the manufacturer presents a certificate of quality. Quality is controlled by State Inspection on Pharmaceutical Quality Unit.</p> <p>All pharmaceutical are subject to licensing which are reviewed by the MOH annually.</p> <p>All imported pharmaceutical products, including contraceptives, are exempt from entrance duty. Condoms are exempted from full customs tariffs and are subject to preferential rate of 5% to 10% of their declared custom value.</p> | <p>Ministry of Health: State Inspection on Pharmaceutical Quality Unit</p> <ul style="list-style-type: none"> ▪ Ministerial Order #143, Procedure of Importing Unregistered Pharmaceuticals ▪ Cabinet of Minister Resolution #15, List of Goods, Imports and Exports Subject to Quotas and Licensing Procedures | Customs procedures and import tariffs do not represent a barrier for the commercial private sector entrance to the Ukrainian market. |
| Advertising and Promotion Regulations | | | |
| Advertising and Promotion | <p>Article 26, Part 3 of the Law on Pharmaceuticals, the Law of Advertising governs pharmaceutical advertising. Article 20 Part of the Law of Advertising prohibits advertising to the general public of medicinal agents that are: (i) available only by a doctor's prescription, (ii) controlled substance, or (iii) contain a narcotic. There are not limits on advertising condoms, other barrier methods and other the counter (OTCs) products.</p> | <p>Ministry of Health: Health Regulations</p> <ul style="list-style-type: none"> ▪ Law on Pharmaceuticals, Article 26, Part 3 ▪ Law of Advertising, Article 20 | <p>Although there are advertising restrictions on prescription drugs, this is not the biggest barrier to providing information directly to consumers. All the Pharmaceutical Companies in Ukraine have OTC pills, permitting them to go around this advertising restriction if they so desire and there are no restrictions on providing generic messages. The primary reasons for limited consumer advertising are: (i) the lack of MOH resources, (ii) lack of MOH capacity to design public awareness campaigns, (iii) Pharmaceutical Companies' preference for communicating with providers. The Pharmaceutical Companies provide (through detailing materials) what little information women/couples receive on FP methods.</p> |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
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| Other Regulations Affecting the Commercial Sector | | | |
| Regulations affecting the commercial sector and market place | | Ministry of Economics | Most of the representatives from the Pharmaceutical Companies interviewed stated they consider the Ukrainian market to be conducive for business. Launching “higher end” products and increasing the number of staff working with contraceptives are signals demonstrating their commitment to stay in the Ukrainian marketplace. Of the 5 Pharmaceutical Companies interviewed, only one expressed concern about the overall legal/regulatory environment. One manufacturer is worried that the current favorable environment if the Government of Ukraine adopts EU regulations that might impose further restriction on advertising and price controls. |
| Regulations affecting the commercial sector and market place | | Ministry of Economics | |
| Price Control | According to a Joint Order from the Ministry of Health and Economics, contraceptive methods-either domestic or imported- are not subject to government price controls. | The Ministry of Health and Ministry of Economics Joint Order of MOH and MOE #265/101, '97 | The Constitution and Health Legislation are silent on price controls for the private and commercial sectors. As a result, the nascent commercial sector is able to charge any prices for services. Prices are targeted for upper middle and upper classes. Consumers pay for the cost of these services through private health insurance schemes or out-of-pocket. |
| Caps on Profit Margins | The law restricts profits margins on pharmaceuticals. Wholesale profit margins are capped at 10% while those for retail are capped at 40%. | | Currently, the cap on profits is not a constraint because profit margins for wholesalers and retailers are both below the legal limit: 10% and 40% respectively. |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
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| Other Regulations Affecting the Commercial Sector (continued) | | | |
| Fee for Service | <p>Article 49 proclaims that the state shall create conditions for efficient and accessible medical care for all citizens. The most important provision of this Article is “medical services shall be free of charge in state and communal health care institutions”.</p> <p>The NFPP admonishes the MOH to provide free contraceptives through FP centers to key target groups: adolescents, women with high-risk pregnancy, Chernobyl victims.</p> | <p>The Ministry of Health and Ministry of Economics Joint Order of MOH and MOE #265/101, '97</p> <p>Ministry of Health:</p> <ul style="list-style-type: none"> ▪ Fundamentals of Health Legislation ('92) ▪ Article 49 of Ukraine Constitution ('96) | <p>There are no restrictions on what the private sector can charge for services. There are however, clear restrictions on charging for services in the public and NGO sectors (see below NGOs). Despite the constitutional right to free medical services in the public sector, almost all clients have to purchase drugs and supplies for the medical care as well as make direct, under-the-table payments to health care providers. Payments are made discreetly in cash or in-kind directly to the service provider. In some cases, the added cost has prevented clients from seeking FP services. The “shadow market” in the public sector has created several outcomes – both negative and positive. On the negative side, it is difficult to ensure quality services. Formal payments would be more convenient for the client. On the positive side, almost everyone pays for services and has become accustomed to paying for services and products. Except for the vulnerable population groups, everyone pays for something for medical services, thereby creating an informal private practice -fee-for-service- within the public sector. The informal payment structure is so entrenched that providers strongly resist any initiatives to changes this system.</p> |

| Regulatory/Policy Area | Description | Authority Responsible | Issues/Outcomes |
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| Restrictions Affecting Non-Profits and Non-government Organizations | | | |
| NGOs | Law on Associations of Citizens, Law on Charity and Charitable Organizations govern the health NGOs. Until recently, NGOs in the FP/RH arena limited their activities to advocacy and information and counseling due to the legal restrictions on their scope. In '04, the laws changed to expand NGOs' role, now permitting NGOs to provide FP/RH services and products. | Ministry of Health Department of Social Services | The recent change in law expanding NGOs scope is important but it is highly unlikely that, in the near future, many will take advantage of these changes. Although NGOs can legally offer services, the MOH yet to create the mechanisms to accredit and license NGOs so they can actually provide medical services. Also, NGOs will not be allowed to charge for services or donated products. With limited international funding to support NGOs, this restriction has effectively squashed any incentive for a NGO to transition from FP advocacy/information activities to FP services. As one successful NGO director said, "Why should I take on the risk to create a medical practice when I can not recoup any of my investment or costs?" Another commented, "Why should I try to compete with the MOH monopoly?" Also, other NGOs directors said it is very difficult to raise capital needed to establish a medical practice. |